



CDSCO Caution on Unapproved New Drugs

[Source: TH](#)

The [Central Drugs Standard Control Organisation \(CDSCO\)](#) has issued a cautionary statement regarding the manufacture and sale of unapproved drugs, particularly emphasising the category of "**New Drugs.**"

- Notably, drugs like **Meropenem**, an antibacterial agent, and **Disodium EDTA**, used to treat calcium overload, were highlighted as examples of such unapproved medications.
- CDSCO emphasised that no new drug should be manufactured for sale without approval from the licensing authority.
- CDSCO is the Central Drug Authority for discharging functions assigned to the Central Government under the [Drugs and Cosmetics Act, 1940](#).
 - Major functions of CDSCO include regulatory control over the import of drugs, approval of new drugs and clinical trials, and approval of certain licences as Central License Approving Authority.

Read more: [Regulatory Issues in Indian Pharmaceutical Sector](#)

PDF Reference URL: <https://www.drishtias.com/printpdf/cdsco-caution-on-unapproved-new-drugs>